UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **September 24, 2019**

Enzo Biochem, Inc.
(Exact Name of Registrant as Specified in Its Charter)

New York
(State or Other Jurisdiction of Incorporation)

001-09974	**13-2866202**
(Commission File Number)	(IRS Employer Identification No.)
527 Madison Avenue **New York, New York**	**10022**
(Address of Principal Executive Offices)	(Zip Code)

(212) 583-0100
(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common stock $0.01 par	ENZ	New York Stock Exchange

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 450 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-1 of this chapter).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other events

On September 24, 2019, Enzo Biochem, Inc. issued a press release titled "New York State Health Department Approves Hepatitis B Virus Quantitative Clinical Assay"

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release of Enzo Biochem, Inc., dated September 24, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ENZO BIOCHEM, INC.

Date: September 24, 2019

By: /s/ Barry W. Weiner
Barry W. Weiner
President

Exhibit 99.1

news release

Enzo Biochem, Inc.
527 Madison Avenue
New York, NY 10022

FOR IMMEDIATE RELEASE

New York State Health Department Approves Hepatitis B Virus Quantitative Clinical Assay

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Approval of AmpiProbe® HBV Viral Load Assay Represents Milestone in Providing Comprehensive Menu of Molecular Diagnostic Tests for Sexually Transmitted Infections

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Continues Company-Wide Commitment to Expand the Market in Diagnostic Testing

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Clear Example of Synergies between Labs and Life Sciences Divisions

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NEW YORK, NY, September 24, 2019 – Enzo Biochem, Inc. (NYSE: ENZ) today announced that its wholly owned subsidiary, Enzo Clinical Labs, Inc. has received New York State approval for its AmpiProbe® HBV viral load monitoring assay for Hepatitis B virus (HBV) based on the Enzo assay's performance versus an FDA-approved comparator product. This is a significant step forward for the Company as the approval of this HBV assay further extends Enzo's portfolio in the viral load monitoring market where the company has already received New York State approval for a viral load monitoring assay for Hepatitis C virus (HCV) and is currently developing a viral load monitoring assay for human immunodeficiency virus (HIV). This expands Enzo's menu, allowing the Company to provide one of the most comprehensive panels for sexual transmitted infection (STI) testing which represent a rapidly growing segment.

This newly approved HBV test will be added to Enzo's existing STI proprietary tests being run at Enzo Clinical Labs, which have replaced those provided by other manufacturers. Apart from being highly effective and economical, the panel is already generating significantly improved margins for those STI tests now being conducted at Enzo's lab. These low cost, high value panels, manufactured under the industry gold standard Good Manufacturing Practices, are forming the basis for Enzo's strategy of providing lower cost reference services to other clinical labs. Developed and manufactured at Enzo Life Sciences, and formatted and validated at Enzo

Clinical Labs, they represent a clear example of the integrated nature of the Company's businesses and the value of their synergies.

Enzo CEO Dr. Elazar Rabbani commented, "With this latest New York State approval, Enzo continues to successfully execute on its plan to provide a cost-effective, comprehensive menu of assays and diagnostic tests addressing the sexually transmitted infections market for women and men. This market is growing rapidly. We are positioning ourselves as a market leader in this category and Enzo will continue to capitalize on our history of innovation as we focus on this market area for growth."

This news follows the Company's recent announcement of New York State Health Department Approval for Gonorrhea and Chlamydia tests for Oral and Rectal Specimens, and the announcement that Enzo was creating a direct to consumer testing business for sexually transmitted infections (STIs). The Company is also developing an additional test for HPV testing in multiple sample types.

According to the Centers for Disease Control and Prevention (CDC), a conservative estimate of the number of persons living with HBV infection in the United States is 850,000 while the actual number may be as high as 2.2 million. Although effective preventative vaccines are available, no curative therapies presently exist for these chronically infected individuals. Significantly, chronic infection with HBV can have serious consequences, including the development of cirrhosis, liver failure and, ultimately, hepatocellular carcinoma, the most common type of liver cancer.

HBV is transmissible by contact with infectious blood or body fluids. One mode of transmission is by percutaneous puncture, typically as a result of syringe use. Another mode of infection is transmission from mother to baby. The virus is also readily transmitted by sexual contact and, according to the CDC, as many as 10-40% of individuals being tested at sexually transmitted disease clinics have evidence of past or current infection by HBV. The CDC also reports that the development of chronic HBV infection is age-related, with 90% of infected infants becoming chronically infected compared to 2-6% of infected adults becoming chronically infected.

The CDC has estimated that the total number of sexually transmitted infections in the United States, including eight common bacterial and viral STIs, is greater than 100 million and that the number of new sexually transmitted infections is around 20 million annually.

About Enzo Biochem

Enzo Biochem is a pioneer in molecular diagnostics, leading the convergence of clinical laboratories, life sciences and intellectual property through the development of unique diagnostic platform technologies that provide numerous advantages over previous standards. A global company, Enzo Biochem utilizes cross-functional teams to develop and deploy products, systems and services that meet the ever-changing and rapidly growing needs of health care today and into the future. Underpinning Enzo Biochem's products and technologies is a broad and deep intellectual property portfolio, with patent coverage across a number of key enabling technologies.

Except for historical information, the matters discussed in this news release may be considered “forward-looking” statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements include declarations regarding the intent, belief or current expectations of the Company and its management, including those related to cash flow, gross margins, revenues, and expenses which are dependent on a number of factors outside of the control of the Company including, inter alia, the markets for the Company’s products and services, costs of goods and services, other expenses, government regulations, litigation, and general business conditions. See Risk Factors in the Company’s Form 10-K for the fiscal year ended July 31, 2018. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that could materially affect actual results. The Company disclaims any obligations to update any forward-looking statement as a result of developments occurring after the date of this press release.

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Contact:

For: Enzo Biochem, Inc.
Steve Anreder, 212-532-3232 or Michael Wachs, CEOcast, Inc., 212-732-4300
steven.anreder@anreder.com mwachs@ceocast.com